

### REMARKS

This amendment and response is in reply to the office action mailed on October 29, 2009 rejecting claims 37-52 and 56. Claims 53-55 and 57-59 were deemed to be allowable if rewritten in independent form, which is noted with appreciation.

The examiner has withdrawn the restriction requirement directed to claims 53-59 and has examined these claims on their merits, which is also noted with appreciation.

#### Rejections under 35 U.S.C. § 103

Claims 37-52 and 56 were rejected under 35 U.S.C. § 103 as unpatentable over Nielsen, WO 98/53771 ("Nielsen").

Nielsen is cited as having a moldable mass of adhesive (a wafer) 7 with an adhesive side. The examiner at page 4 interprets Nielsen to provide the wafer 7 with a second adhesive surface and states: "A central part of the second surface of said wafer 7 surrounding said stoma-accommodating hole is provided with an adhesive layer in the form of a moldable backing thereon," citing to Nielsen at Figures 3, 7, and page 8, lines 10 through 14. The examiner's position is that the moldable backing is compatible with the first adhesive surface "inasmuch as Nielsen discloses that it is sprayed on the adhesive wafer second surface and allows the temporary adhesion of the first surface to the second surface five shown in Figure 7." We respectfully disagree.

Regarding the moldable backing: Nielsen provides at page 8, lines 10-13:

A mouldable backing may e.g. be a Parafilm® or made from a polymer solution which is sprayed on the surface and protects the surface of the adhesive against dissolution by secretions from the stoma **and** prevent a tacky surface on the side facing the bag."

Emphasis added.

Parsing the disclosure of Nielsen at page 8, lines 10-13 indicates that the moldable backing is Parafilm® or it is made from a polymer solution. One of ordinary skill in the art would understand that Parafilm® is a highly waterproof and water resistant sheet of plastic material made by the Pechiney Plastic Packaging Company of Chicago, Ill. -- it is commonly employed to seal test tubes, beakers, jars and the like. Information related to Parafilm® is

available on the Internet, for example, by conducting a Google search for the term "parafilm." In any regard, one of ordinary skill the art understands that Parafilm® is a non-adhesive plastic film.

The polymer solution referenced by Nielsen at page 8 is sprayed on the surface of the wafer and protects the surface of the adhesive against dissolution by secretions from the stoma (as noted by the examiner) **AND** prevents a tacky surface on the side of the wafer that faces the bag, as expressly disclosed by Nielsen at page 8, lines 12-13. The polymer solution referenced by Nielsen at page 8 both protects the adhesive from degradation and prevents tackiness. The polymer solution cannot be an adhesive if it prevents tackiness, as Nielsen expressly discloses. Thus, the moldable backing does not provide an adhesive layer since it is either Parafilm® or it prevents a tacky surface on the side of the wafer that faces the bag.

Consequently, the applicant respectfully disagrees with the examiner's position stated at page 4 of the office action that the moldable backing is compatible with the first adhesive surface "inasmuch as Nielsen discloses that it is sprayed on the adhesive wafer second surface and allows the temporary adhesion of the first surface to the second surface 5 shown in Figure 7." Applicant respectfully notes that Figure 7 only illustrates an inner rim of the wafer 7 everted to touch the opposite side. Nothing in the disclosure or in Figure 7 suggests that this contact is an adhesive contact that "allows the temporary adhesion of the first surface to the second surface 5" as asserted by the examiner. In fact, Nielsen teaches away from adhering the first adhesive surface to the second surface at page 12, lines 3-6 where the enlargement of the hole is carried out by rolling the inner ring, which after release, will "unroll and seal against the stoma."

With this response, independent claim 37 has been amended to require an adhesive wafer extending between an outer rim and an inner rim defining a hole for accommodating a stoma and including a first moisture-absorbing adhesive surface for securing the appliance to a user's skin and a second surface having a removable release liner, a portion of the adhesive wafer surrounding the stoma having balanced plastic and elastic properties, a central part of the second surface of the adhesive wafer having a hydrophobic adhesive layer thereon that is compatible with the first adhesive surface; wherein the stoma-accommodating hole is enlarged by removing the removable release liner from the second surface of the adhesive wafer to expose the hydrophobic adhesive layer, rolling the inner rim of the adhesive wafer toward the outer rim, and

adhering the first adhesive surface to said exposed hydrophobic adhesive layer of the second surface.

Nielsen does not teach or suggest the stoma-accommodating hole is enlarged by removing the removable release liner from the second surface of the adhesive wafer to expose the hydrophobic adhesive layer, as required by amended independent claim 37. Nielsen provides the first adhesive surface with a release liner 15, but the second surface is not an adhesive surface (and thus would not benefit from a release liner). The moldable backing of Nielsen is not a removable release liner. Layer 5 (Figure 4) of Nielsen is a sealing member, and this sealing member 5 is not removed when the inner rim of the adhesive wafer 7 is everted (Figure 7).

Nielsen does not teach or suggest rolling the inner rim of the adhesive wafer toward the outer rim, and adhering the first adhesive surface to said exposed hydrophobic adhesive layer of the second surface, as required by amended independent claim 37. In fact, Nielsen teaches away from adhering the first adhesive surface to the exposed adhesive layer of the second surface by disclosing at page 12, lines 3-6 that the enlargement of the hole is carried out by everting the ring via rolling the inner ring, which after release will unroll and seal against the stoma.

Thus, it is believed that amended independent claim 37 is not rendered obvious over Nielsen. Claims 39-47 further define patently distinct amended independent claim 37 and are also believe to be allowable.

Independent claim 50 has been amended to require a removable release liner disposed over the hydrophobic adhesive layer, the method comprising: removing said release liner from the hydrophobic adhesive layer; enlarging the hole to adapt to a size of the stoma by rolling the inner rim of the hole toward an outer perimeter of the adhesive wafer; adhering the hydrophobic adhesive layer to the first adhesive surface. Nielsen fail to teach or suggest a removable release liner disposed over the hydrophobic adhesive layer, and adhering the hydrophobic adhesive layer to the first adhesive surface.

Thus, it is believed that amended independent claim 50 is not rendered obvious over Nielsen.

Independent claim 51 has been amended to require enlarging the first hole of the sealing member by rolling the inner rim of the hole of the sealing member toward an outer perimeter of the sealing member; adapting the first hole of the sealing member to the size of the stoma;

Applicants : Ciok et al.  
Serial No. : 10/541,823  
Filed : July 11, 2005  
Page : 10 of 10

Attorney Docket No.: 2002029-US

adhering the first adhesive surface to the hydrophobic adhesive layer of the second surface of the sealing member. Nielsen fail to teach or suggest adhering the first adhesive surface to the hydrophobic adhesive layer of the second surface as required by amended independent claim 51.

Thus, it is believed that amended independent claim 51 is not rendered obvious over Nielsen.

Claims 53-55 further define amended independent claim 15 and were previously deemed to be allowable.

Claim 60 is newly presented as an independent claim that recites a portion of the allowable subject matter of claim 53.

#### CONCLUSION

Applicant respectfully asserts that the pending claims are in condition for allowance. The Examiner is respectfully requested to telephone the undersigned if issues remain outstanding.

No additional fees are believed due for the addition of claim 60. However, the office is authorized to charge any fees actually due and credit any overpayment to deposit account 50-4439.

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Respectfully submitted,  
Ciok, et al.

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/Nick Baumann/  
Nick Baumann, Reg. No. 56,161  
Senior Patent Counsel  
Coloplast Corp., Coloplast A/S  
Customer No. 69289  
Telephone: 612 287 4178